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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,285	04/11/2006	Wolfgang E. Gallwitz	432722003800	4063
25225 7590 11/28/2008 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER WINSTON, RANDALL O	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 11/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,285	Applicant(s) GALLWITZ ET AL.	
	Examiner Randall Winston	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008 and 23 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8,10,12 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2,8,10,12,16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0606</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

. Election/Restrictions

Applicant's election of Group I and the election of species of an isolated flavonoid (i.e. isoginkgetin) in the reply filed on 10/29/2008 and 07/23/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Readable claims 1-2, 8, 10, 12 and 16 have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 8, 10, 12 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 2 are rendered vague and indefinite by the term "flavanoid." The above term is misspelled. The above term should be replaced with the correct spelling of "flavonoid." Correction is required.

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 8, 10, 12 and 16 are rejected under 35 USC 112, first paragraph, because the specification, while enabling for a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with isoginkgetin derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject, the specification does not enable any person in the art in preparing a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with any and/or all isolated flavonoid derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject. The specification does not enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

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The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with any and/or all isolated flavonoid derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject. Applicant has reasonably demonstrated in the examples on pages 6-7 of the specification, a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with isoginkgetin derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises

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facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with any and/or all isolated flavonoid derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject.

Furthermore, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with any and/or all isolated flavonoid derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject. For example, Haines et al. teach (see, e.g. US 20040076691, see entire patent including paragraph 0028, 0089, 0099) flavonoids such as isoginkgetin, ginkgetin and sequoiaflavone derived from *Ginkgo biloba* utilized as an anti-inflammatory. Thus, the art is silent regarding the efficacy of applicant's method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with any and/or all isolated flavonoid derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject. Therefore, applicant's claimed method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure

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related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with any and/or all isolated flavonoid derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject is unpredictable in the art. In addition, applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness and/or alopecia caused by radiation or chemotherapy which method comprises providing said area with any and/or all isolated flavonoid derived from *Ginkgo biloba* to stimulate the growth of hair in an area on the surface of a hair-bearing subject.

Therefore, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 8, 10 and 16 are rejected under 35 USC 102(b) as being anticipated by Kondo et al. (JP 410287531A, see abstract).

Applicant claims a method to stimulate the growth of hair in an area on the surface of a hair-bearing subject wherein the said surface comprises facial or coiffure related hair and wherein the subject is afflicted with male pattern baldness which method comprises providing said area with at least one and/or any and/or all isolated flavonoid derived from *Ginkgo biloba*.

Kondo anticipates the claimed invention because Kondo teaches a topical cosmetic composition comprising of at least one flavonoid components and/or flavonoid active ingredients derived from *Ginkgo biloba* applied to a subject in need thereof skin and/or head skin for hair restoring and/or having a hair growing effect whereas when Kondo's topical cosmetic composition is applied to the skin and/or head skin for hair restoring and/or having a hair growing effect, Kondo's topical cosmetic composition would also inherently stimulate the growth of hair in an area on the surface of a subject afflicted with male pattern baldness (see, e.g. abstract). Therefore, the reference is deemed to anticipate the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655